

Application No. 08/960,557

Docket No.: 50454-56103USCIP

LISTING OF THE CLAIMS

1-28. (Canceled)

29. (Currently amended) A method of treating cholesterol disorders with an intermediate release nicotinic acid formulation ~~without causing treatment limiting hepatotoxicity, elevations in uric acid, or glucose levels such that use of said formulation is discontinued~~ comprising:

orally administering once per day an effective amount of said formulation for treating said disorder, said formulation having a dissolution curve similarity fit factor F2 of at least about 79, and an *in vitro* dissolution profile, when measured in a type I dissolution apparatus (basket) according to U.S. Pharmacopoeia XXII, in about 37°C in deionized water at about 100 rpm, as follows:

(a) less than about 15% of the nicotinic acid is released after about 1 hour in the apparatus;

(b) between about 15% and about 30% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 30% and about 45% of the nicotinic acid is released after about 6 hours in the apparatus;

(d) between about 40% and about 60% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 50% and about 75% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

30. (Previously presented) The method of claim 29 wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

31. (Canceled)

32. (Previously presented) The method of claim 29, wherein said formulation is a tablet.

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33. (Previously presented) The method of claim 32, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375 gm, about 500 mg, and about 750 mg.

34. (Previously presented) The method of claim 29, wherein the once per day dose is administered during the evening or at night.

35. (Currently amended) The method of claim 29, wherein the *in vitro* dissolution profile is as follows:

(a) between about 9.6% and about 13.8% of the nicotinic acid is released after about 1 hour in the apparatus;

(b) between about 21.2% and about 27.8% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 35.1% and about 44.2% of the nicotinic acid is released after about 6 hours in the apparatus;

(d) between about 45.6% and about 58.5% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 56.2% and about 72% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

36. (Previously presented) The method of claim 35, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

37. (Canceled)

38. (Previously presented) The method of claim 35, wherein said formulation is a tablet.

39. (Previously presented) The method of claim 38, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375 mg, about 500 mg, and about 750 mg.

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40. (Previously presented) The method of claim 35, wherein the once per day dose is administered during the evening or at night.

41. (Previously presented) The method of claim 29, wherein the *in vitro* dissolution profile is as follows:

(a) between about 9.8% and about 12.3% of the nicotinic acid is released after about 1 hour in the apparatus;

(b) between about 20.9% and about 26.7% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 35.3% and about 44.1% of the nicotinic acid is released after about 6 hours in the apparatus;

(d) between about 44.8% and about 58.7% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 59.5% and about 70.7% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

42. (Previously presented) The method of claim 41, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

43. (Canceled)

44. (Previously presented) The method of claim 41, wherein said formulation is a tablet.

45. (Previously presented) The method of claim 44, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375 mg, about 500 mg, and about 750 mg.

46. (Previously presented) The method of claim 41, wherein the once per day dose is administered during the evening or at night.

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47. (Currently amended) A method of treating cholesterol disorders with an intermediate release nicotinic acid formulation ~~without causing treatment-limiting hepatotoxicity, elevations in uric acid or glucose levels such that use of said formulation is discontinued~~, comprising:

orally administering once per day an effective amount of said formulation for treating said disorder, said formulation having a dissolution curve similarity fit factor F2 of at least 44, and an *in vitro* dissolution profile, when measured in a type I dissolution apparatus (basket), according to U.S. Pharmacopiea XXII, in about 37°C in deionized water at about 100 rpm, as follows:

- (a) less than about 15% of the nicotinic acid is released after about 1 hour in the apparatus;
- (b) between about 15% and about 30% of the nicotinic acid is released after about 3 hours in the apparatus;
- (c) between about 30% and about 45% of the nicotinic acid is released after about 6 hours in the apparatus;
- (d) between about 40% and about 60% of the nicotinic acid is released after about 9 hours in the apparatus;
- (e) between about 50% and about 75% of the nicotinic acid is released after about 12 hours in the apparatus; and
- (f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

48. (Previously presented) The method of claim 47, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

49. (Previously presented) The method of claim 47, wherein said formulation is a tablet.

50. (Previously presented) The method of claim 49, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375 mg, about 500 mg, about 750 mg and about 1000 mg.

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51. (Previously presented) The method of claim 47, wherein the once per day dose is administered during the evening or at night.

52. (Previously presented) The method of claim 47, wherein the *in vitro* dissolution profile is as follows:

(a) between about 9.6% and about 13.8% of the nicotinic acid is released after about 1 hour in the apparatus;

(b) between about 21.2% and about 27.8% of the nicotinic acid is released after about 3 hours in the apparatus;

(c) between about 35.1% and about 44.2% of the nicotinic acid is released after about 6 hours in the apparatus;

(d) between about 45.6% and about 58.5% of the nicotinic acid is released after about 9 hours in the apparatus;

(e) between about 56.2% and about 72% of the nicotinic acid is released after about 12 hours in the apparatus; and

(f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

53. (Previously presented) The method of claim 52, wherein approximately 100% of the nicotinic acid is released after about 20 hours in the apparatus.

54. (Previously presented) The method of claim 52, wherein said formulation is a tablet.

55. (Previously presented) The method of claim 54, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375 mg, about 500 mg, and about 750 mg.

56. (Previously presented) The method of claim 53, wherein the once per day dose is administered during the evening or at night.

57. (Previously presented) The method of claim 47, wherein the *in vitro* dissolution profile is as follows:

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- (a) between about 9.8% and about 12.3% of the nicotinic acid is released after about 1 hour in the apparatus;
- (b) between about 20.9% and about 26.7% of the nicotinic acid is released after about 3 hours in the apparatus;
- (c) between about 35.3% and about 44.1% of the nicotinic acid is released after about 6 hours in the apparatus;
- (d) between about 44.8% and about 58.7% of the nicotinic acid is released after about 9 hours in the apparatus;
- (e) between about 59.5% and about 70.7% of the nicotinic acid is released after about 12 hours in the apparatus; and
- (f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

58. (Previously presented) The method of claim 57, wherein approximately 100% of the nicotinic acid is released about 20 hours in the apparatus.

59. (Previously presented) The method of claim 57, wherein said formulation is a tablet.

60. (Previously presented) The method of claim 59, wherein said tablet contains nicotinic acid in an amount selected from the group consisting of about 375 mg, about 500 mg, about 750 mg and about 1000 mg.

61. (Previously presented) The method of claim 57, wherein the once per day dose is administered during the evening or at night.